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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,092	01/18/2002	Suzanne Fuqua	HO-P02102US2	5838

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FULBRIGHT & JAWORSKI, LLP
1301 MCKINNEY
SUITE 5100
HOUSTON, TX 77010-3095

EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	9

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/052,092	Applicant(s) FUQUA ET AL.	
	Examiner Valarie Bertoglio	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30days* ~~MONTH~~(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to a nucleic acid with an A908G mutation, classified in class 536, subclass 23.1.

II. Claim 2, drawn to a polypeptide with a K303R substitution, classified in class 530, subclass 350.

III. Claims 3-10, 12-14, 16-20 and 22, drawn to a method of detecting breast cancer using a nucleic acid assay and a kit comprising a nucleic acid primer for carrying out said method, classified in class 435, subclass 6.

IV. Claims 3-9,11-13,15,16-19,21 and 24, drawn to a method of detecting breast cancer using immunoassay to detect an A908G mutation in an estrogen receptor alpha nucleic acid and a monoclonal antibody designed to bind an estrogen receptor alpha nucleic acid comprising an A908G mutation, classified in class 435, subclass 7.1.

V. Claim 23, drawn to a monoclonal antibody that binds an acetylated estrogen receptor alpha polypeptide, classified in class 530, subclass 387.1.

VI. Claims 25-32, drawn to a method of in vivo gene therapy to correct a G mutation at nucleotide 908 of then estrogen receptor alpha nucleic acid sequence, classified in class 514, subclass 44.

VII. Claims 33 and 34, drawn to a method of in vivo protein therapy to prevent breast cancer comprising administering a polypeptide comprising an estrogen receptor alpha sequence comprising a lysine residue at amino acid 303, classified in class 514, subclass 2.

VIII. Claim 35, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vitro by admixing the candidate modulator with a compound or cell, classified in class 435, subclass 4.

IX. Claim 35, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vivo, classified in class 424, subclass 9.2.

X. Claims 36-44, drawn to a method of identifying a modulator of a mutant estrogen receptor alpha K303R polypeptide in vitro using recombinant cells comprising a vector encoding mutant estrogen receptor alpha K303R polypeptide and a vector comprising an estrogen-responsive regulatory element operably linked to a reporter polynucleotide, classified in class 435, subclass 6.

XI. Claims 45 and 53, drawn to a method of treating breast cancer using an antagonist of a mutant estrogen receptor alpha K303R polypeptide, classified in class 514, subclass 2.

XII. Claims 46-52, drawn to an in vitro method of identifying a polypeptide that interacts with an estrogen receptor alpha K303R polypeptide comprising introducing into a cell a vector comprising a chimeric estrogen receptor alpha K303R polypeptide and a DNA binding domain and a vector comprising a polynucleotide encoding a chimeric comprising a candidate polypeptide and a DNA activation domain and assaying for interaction, classified in class 435, subclass 7.1.

XIII. Claim 54-56, drawn to an in vitro method of identifying a polypeptide that interacts with an estrogen receptor alpha K303R polypeptide comprising obtaining and affinity tagged estrogen receptor alpha K303R polypeptide, introducing said polypeptide to a plurality of bacteriophage that produce

candidate polypeptides and determining binding, classified in class 435, subclass 5.

XIV. Claims 57-59, drawn to an in vivo method of identifying a compound for treatment for breast cancer, classified in class 424, subclass 9.2.

XV. Claims 60 and 61, drawn to a compound having therapeutic activity for the treatment of breast cancer, unclassifiable.

XVI. Claims 62 and 63, drawn to a transgenic mouse comprising an estrogen receptor alpha having an A908G mutation, classified in class 800, subclass 18.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are patentably distinct because, the nucleic acid can be used as a probe, while the protein can be used to generate antibody. The nucleic acid and the protein are structurally and functionally distinct and have different purpose. The nucleic acid does not require the protein and the protein does not require the nucleic acid. Furthermore, the nucleic acid and the protein are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the protein of Invention II together.

Invention I and Inventions III or IV are patentably distinct because the nucleic acid can be used to make a transgenic animal while the methods of either Invention III or IV can be used to detect a mutation associated with breast cancer. The nucleic acid does not require the methods and the methods do not require the nucleic acid. Furthermore, the nucleic acid and the protein are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the methods of either Invention III or Invention IV together.

Inventions I and V are patentably distinct because, the nucleic acid can be used as a probe, while the antibody can be used to detect protein. The nucleic acid and the antibody are structurally and functionally distinct and have different purpose. The nucleic acid does not require the antibody and the antibody does not require the nucleic acid. Furthermore, the nucleic acid and the antibody are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the antibody of Invention V together.

Invention I and Inventions VI or VII are patentably distinct because the nucleic acid can be used to make a transgenic animal while the methods of either Invention VI or VII can be used to correct a mutation associated with breast cancer. The nucleic acid does not require the methods and the methods do not require the nucleic acid. Furthermore, the nucleic acid and the methods are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the methods of either Invention VI or Invention VII together.

Invention I and Inventions VIII-X, XII, XIII, or XIV are patentably distinct because the nucleic acid can be used to make a transgenic animal while the methods of any of Inventions VIII-X, XII, XIII, or XIV can be used to identify a compound that interacts with or modulates estrogen receptor alpha K303R or a compound that treats breast cancer (Invention XIV). The nucleic acid does not require the methods and the methods do not require the nucleic acid. Furthermore, the nucleic acid and the methods are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the methods of any of Inventions VIII-X, XII, XIII, or XIV together.

Inventions I and XI are patentably distinct because the nucleic acid can be used to make a transgenic animal while the methods of Invention XI can be used to treat breast cancer.

The nucleic acid does not require the methods and the methods do not require the nucleic acid. Furthermore, the nucleic acid and the methods are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the methods of Invention XI together.

Inventions I and XV are patentably distinct because, the nucleic acid can be used as a probe, while the compound can be used to treat breast cancer. The nucleic acid and the compound are structurally and functionally distinct and have different purpose. The nucleic acid does not require the compound and the compound does not require the nucleic acid. Furthermore, the nucleic acid and the compound are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the compound of Invention XV together.

Inventions I and XVI are patentably distinct because, the nucleic acid can be used as a probe, while the transgenic mice can be used to develop an animal model of breast cancer. The nucleic acid and the mice are structurally and functionally distinct and have different purpose. Furthermore, the nucleic acid and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention I and the transgenic mouse of Invention XVI together.

Invention II and Inventions III or IV are patentably distinct because the polypeptide can be used in vitro to identify interacting proteins while the methods of either Invention III or IV can be used to detect a mutation associated with breast cancer. The polypeptide does not require the methods and the methods do not require the nucleic acid. Furthermore, the nucleic acid and the methods are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention II and the methods of either Invention III or Invention IV together.

Inventions II and V are patentably distinct because, the polypeptide be used in vitro to identify interacting proteins, while the antibody can be used to detect protein. The polypeptide and the antibody are structurally and functionally distinct and have different purpose. The protein does not require the antibody and the antibody does not necessarily require the polypeptide of Invention II. Furthermore, the polypeptide and the antibody are classified differently. It would require undue burden on the part of the examiner to search the polypeptide of Invention II and the antibody of Invention V together.

Invention II and Inventions VI or VII are patentably distinct because the polypeptide can be used to generate antibody while the methods of either Invention VI or VII can be used to correct a mutation associated with breast cancer. The polypeptide does not require the methods and the methods do not require the polypeptide. Furthermore, the polypeptide and the methods are classified differently. It would require undue burden on the part of the examiner to search the nucleic acid of Invention II and the methods of either Invention VI or Invention VII together.

Invention II and Inventions VIII-X, XII, XIII, or XIV are patentably distinct because the polypeptide can be used to generate antibody while the methods of any of Inventions VIII-X, XII, XIII, or XIV can be used to identify a compound that interacts with or modulates estrogen receptor alpha K303R or a compound that treats breast cancer (Invention XIV). The polypeptide does not require the methods and the methods do not require the polypeptide. Furthermore, the polypeptide and the methods are classified differently. It would require undue burden on the part of the examiner to search the polypeptide of Invention II and the methods of any of Inventions VIII-X, XII, XIII, or XIV together.

Inventions II and XI are patentably distinct because the polypeptide can be used to generate antibody while the methods of Invention XI can be used to treat breast cancer. The polypeptide does not require the methods and the methods do not require the polypeptide.

Furthermore, the polypeptide and the methods are classified differently. It would require undue burden on the part of the examiner to search the polypeptide of Invention II and the methods of Invention XI together.

Inventions II and XV are patentably distinct because the polypeptide can be used to generate antibody while the compound can be used to treat breast cancer. The polypeptide and the compound are structurally and functionally distinct and have different purpose. The polypeptide does not require the compound and the compound does not require the polypeptide. Furthermore, polypeptide and the compound are classified differently. It would require undue burden on the part of the examiner to search the polypeptide of Invention II and the compound of Invention XV together.

Inventions II and XVI are patentably distinct because, the polypeptide can be used as a to generate an antibody, while the transgenic mice can be used to develop an animal model of breast cancer. The polypeptide and the mice are structurally and functionally distinct and have different purpose. Furthermore, the polypeptide and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the polypeptide of Invention II and the transgenic mouse of Invention XVI together.

The methods of each of Inventions III and IV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Invention III is drawn to methods of nucleic acid assay while Invention IV is drawn to methods of Immunoassay. The methods of each invention are independent and distinct and are classified differently. It would require undue burden on the part of the examiner to search the methods of Invention III or Invention IV together.

Inventions III or IV and Invention V are patentably distinct because the methods of Inventions III or IV can be used to detect a mutation while the antibody can be used to isolate protein. The methods do not necessarily require the antibody and the antibody does not require the methods. Furthermore, the methods and the antibody are classified differently. It would require undue burden on the part of the examiner to search the methods of either Invention III or IV and the antibody of Invention V together.

Inventions III or IV and Inventions VI or VII are patentably distinct because the methods of Inventions III or IV can be used to detect a mutation while the methods of either Invention VI or VII can be used to correct a mutation associated with breast cancer. The methods steps of Inventions III or IV are independent of and differ from the methods steps of either of Inventions VI or VII. The methods of each invention require different technical considerations. The purpose of Inventions III and IV are different from the purpose of Inventions VI and VII. Furthermore, the methods of each invention are classified differently. It would require undue burden on the part of the examiner to search the methods of Inventions III or IV and the methods of either Invention VI or Invention VII together.

Invention III or IV and Inventions VIII-X, XII, XIII, or XIV are patentably distinct because the methods of Inventions III or IV can be used to detect a mutation while the methods of any of Inventions VIII-X, XII, XIII, or XIV can be used to identify a compound that interacts with or modulates estrogen receptor alpha K303R or a compound that treats breast cancer (Invention XIV). The methods steps of Inventions III and IV are independent of and differ from the methods steps of either of Inventions VIII-X, XII, XIII, or XIV. The methods of each invention require different technical considerations. Furthermore, the methods of each invention are classified differently. It would require undue burden on the part of the examiner to search the methods of Invention III or IV and the methods of any of Inventions VIII-X, XII, XIII, or XIV together.

Inventions III or IV and Invention XI are patentably distinct because the methods of Inventions III or IV can be used to detect a mutation while the methods of Invention XI can be used to treat breast cancer. The methods steps of Inventions III and IV are independent of and differ from the methods steps of Invention XI. The methods of each invention require different technical considerations. Furthermore, the methods of each invention are classified differently. It would require undue burden on the part of the examiner to search the methods of Invention III or IV and the methods of Invention XI together.

Inventions III or IV and Invention XV are patentably distinct because the methods of Inventions III or IV can be used to detect a mutation while the compound can be used to treat breast cancer. The methods do not require the compound and the compound does not require the methods. Furthermore, methods and the compound are classified differently. It would require undue burden on the part of the examiner to search the methods of either of Inventions III or IV and the compound of Invention XV together.

Inventions III or IV and Invention XVI are patentably distinct because the methods of Inventions III or IV can be used to detect a mutation, while the transgenic mice can be used to develop an animal model of breast cancer. The methods do not require the mice and the mice do not require the methods. Furthermore, the methods and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the methods of Invention III or IV and the transgenic mouse of Invention XVI together.

Invention V and Inventions VI or VII are patentably distinct because the antibody can be used to isolate protein in vitro while the methods of either Invention VI or VII can be used to correct a mutation associated with breast cancer. The antibody does not require the methods and the methods do not require the antibody. Furthermore, the antibody and the methods are

classified differently. It would require undue burden on the part of the examiner to search the antibody of Invention V and the methods of either Invention VI or Invention VII together.

Invention V and Inventions VIII-X, XII, XIII, or XIV are patentably distinct because the antibody can be used to isolate protein in vitro while the methods of any of Inventions VIII-X, XII, XIII, or XIV can be used to identify a compound that interacts with or modulates estrogen receptor alpha K303R or a compound that treats breast cancer (Invention XIV). The antibody does not require the methods and the methods do not require the antibody. Furthermore, the antibody and the methods are classified differently. It would require undue burden on the part of the examiner to search the antibody of Invention V and the methods of any of Inventions VIII-X, XII, XIII, or XIV together.

Inventions V and XI are patentably distinct because the antibody can be used to isolate protein in vitro while the methods of Invention XI can be used to treat breast cancer. The antibody does not require the methods and the methods do not require the antibody. Furthermore, the antibody and the methods are classified differently. It would require undue burden on the part of the examiner to search the antibody of Invention V and the methods of Invention XI together.

Inventions V and XV are patentably distinct the antibody can be used to isolate protein in vitro while the compound can be used to treat breast cancer. The antibody and the compound are structurally and functionally distinct and have different purpose. The polypeptide does not require the compound and the compound does not require the polypeptide. Furthermore, polypeptide and the compound are classified differently. It would require undue burden on the part of the examiner to search the antibody of Invention V and the compound of Invention XV together.

Inventions V and XVI are patentably distinct because, the antibody can be used to isolate protein in vitro while the transgenic mice can be used to develop an animal model of breast cancer. The antibody and the mice are structurally and functionally distinct and have different purpose. Furthermore, the antibody and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the antibody of Invention V and the transgenic mouse of Invention XVI together.

The methods of each of Inventions VI and VII are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Invention VI is drawn to methods of gene therapy. Invention VII is drawn to methods of protein therapy. The methods are classified differently and it would require undue burden on the part of the examiner to search the methods of Inventions VI and VII together.

Invention VI or VII and Inventions VIII-X, XII, XIII, or XIV are patentably distinct because the methods of Inventions VI or VII can be used to treat disease while the methods of any of Inventions VIII-X, XII, XIII, or XIV can be used to identify a compound that interacts with or modulates estrogen receptor alpha K303R or a compound that treats breast cancer (Invention XIV). The methods steps of Inventions VI or VII are independent of and differ from the methods steps of any of Inventions VIII-X, XII, XIII, or XIV. The methods of each invention require different technical considerations. Furthermore, the methods of each invention are classified differently. It would require undue burden on the part of the examiner to search the methods of Invention VI or VII and the methods of any of Inventions VIII-X, XII, XIII, or XIV together.

Inventions VI or VII and Invention XI are patentably distinct because the methods of Inventions VI or VII use nucleic acid encoding a normal estrogen receptor alpha gene (Invention VI) or a normal estrogen receptor alpha polypeptide while the methods of Invention XI use other

proteins to treat breast cancer. The methods steps of Invention VI are independent of and differ from the methods steps of Invention XI. The methods of each invention require different technical considerations. It would require undue burden on the part of the examiner to search the methods of Invention III or IV and the methods of Invention XI together.

Inventions VI or VII and Invention XV are patentably distinct because the methods of Inventions VI or VII can be used to treat disease using nucleic acid encoding a normal estrogen receptor alpha gene (Invention VI) or a normal estrogen receptor alpha polypeptide (Invention VII) while the compound of Invention XV may act independently of the estrogen receptor alpha. Thus, the methods are patentably distinct and are independent of one another. Furthermore, methods and the compound are classified differently. It would require undue burden on the part of the examiner to search the methods of either of Inventions VI or VII and the compound of Invention XV together.

Inventions VI or VII and Invention XVI are patentably distinct because the methods of Inventions VI or VII can be used to treat disease, while the transgenic mice can be used to develop an animal model of breast cancer. The methods do not require the mice and the mice do not require the methods. Furthermore, the methods and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the methods of Inventions VI or VII and the transgenic mouse of Invention XVI together.

The methods of each of Inventions VIII-X, XII, XIII, or XIV are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. Invention VIII involves screening for modulators of estrogen receptor alpha K303R by admixing the candidate modulator with a compound or cell in vitro. Invention X involves screening for modulators of estrogen receptor alpha K303R using recombinant cells to detect estrogen

receptor activity using reporter gene expression. Invention XII involves screening for compounds that interact with estrogen receptor alpha K303R comprising a 2-hybrid screen. Invention XIII involves screening for compounds that interact with estrogen receptor alpha K303R comprising determining binding of estrogen receptor alpha K303R with candidates from a bacteriophage expression library. Invention XIV involves an in vivo method of identifying a treatment for breast cancer wherein the compound does not necessarily interact or modulate estrogen receptor alpha K303R. The methods of each invention are independent and one is not necessary for the other. Each invention is classified differently. It would require undue burden on the part of the examiner to search the methods of Inventions VIII-X, XII, XIII, or XIV together.

The methods of Inventions VIII-X, XII, XIII, or XIV and the methods Invention XI are materially different and plurally independent from each other because each is practiced with materially different process steps and technical considerations and requires materially distinct protocols and reagents. The methods of Inventions VIII-X, XII, XIII, or XIV can be used to identify potential treatments for breast cancer associated with estrogen receptor alpha K303R while the methods of Invention XI are drawn to treating breast cancer. The methods steps of the inventions are different, independent and distinct and the inventions are classified separately. It would require undue burden on the part of the examiner to search the any of the methods of Inventions VIII-X, XII, XIII, or XIV and Invention XI together.

The methods of Inventions VIII-X, XII, XIII, or XIV and the compound of Invention XV are patentably distinct because the methods can be used identify compounds that interact with or modulate estrogen receptor alpha K303R but are not effective in treating cancer while the compounds of Invention XV may not interact or affect estrogen receptor alpha K303R. The inventions are classified separately and it would require undue burden on the part of the

examiner to search the any of the methods of Inventions VIII-X, XII, XIII, or XIV and Invention XV together.

Invention VIII-X, XII, XIII, or XIV and Invention XVI are patentably distinct because the methods of Inventions VIII-X, XII, XIII, or XIV can be used to identify modulators or proteins that interact with estrogen receptor alpha K303R, while the transgenic mice can be used to develop an animal model of breast cancer. The methods do not require the mice and the mice do not require the methods. Furthermore, the methods and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the methods of Inventions VIII-X, XII, XIII, or XIV and the transgenic mouse of Invention XVI together.

Invention XI and Invention XV are patentably distinct because the methods of Invention XI can be used to treat breast cancer using antagonists of estrogen receptor alpha K303R, while the compounds of Invention XV may not modulate estrogen receptor alpha K303R and can be used to treat other cancers. Furthermore, Invention XV encompasses a vast array of compounds including nucleic acids, proteins, antibodies, or other drugs that are classified differently and are independent and distinct from those used in the methods of Invention XI. It would require undue burden on the part of the examiner to search the methods of Invention XI and the compound of Invention XV together.

Invention XI and Invention XVI are patentably distinct because the methods of Invention XI can be used to identify modulators or compounds that interact with estrogen receptor alpha K303R, while the transgenic mice can be used to develop an animal model of breast cancer. The methods do not require the mice and the mice do not require the methods. Furthermore, the methods and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the methods of Invention XI and the transgenic mouse of Invention XVI together.

Invention XV and Invention XVI are patentably distinct because the compound of Invention XV can be used to treat disease, while the transgenic mice of Invention XVI can be used to develop an animal model of breast cancer. The compound does not require the mice and the mice do not require the compound. Furthermore, the compound and the transgenic mouse are classified differently. It would require undue burden on the part of the examiner to search the compound of Invention XV and the transgenic mouse of Invention XVI together.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A) SEQ ID NO: 15

B) SEQ ID NO: 16

C) SEQ ID NO: 17

D) SEQ ID NO: 18

E) SEQ ID NO: 33

F) SEQ ID NO: 34

G) SEQ ID NO: 35

H) SEQ ID NO: 36

I) SEQ ID NO: 37

J) SEQ ID NO: 38

K) SEQ ID NO: 39

L) SEQ ID NO: 40

M) SEQ ID NO: 41

N) SEQ ID NO: 42

O) SEQ ID NO: 43

P) SEQ ID NO: 44

Q) SEQ ID NO: 45

R) SEQ ID NO: 46

S) SEQ ID NO: 47

T) SEQ ID NO: 48

U) SEQ ID NO: 49

V) SEQ ID NO: 22

W) SEQ ID NO: 26

X) SEQ ID NO: 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of Group A-G and Group H-X for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic to Group A-G. Claims 36-42 are generic to Group H-X.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species

to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is 703-305-5469. The examiner can normally be reached on 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds can be reached on 703-305-4051. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Valarie Bertoglio
Patent Examiner

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

DEBORAH J. REYNOLDS
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600